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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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08/455,975 05/31/95 RUBIN

J	10359/299/NI
EXAMINER	

HM11/0604

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ATTUNE	PAPER NUMBER
08/455,975	12

1646  
DATE MAILED:

06/04/98

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

Responsive to communication(s) filed on 08 May 1998

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

Shortened statutory period for response to this action is set to expire 1 month(s), ~~or thirty days~~, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 36(a).

#### Disposition of Claims

Claim(s) 38-120 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
Claim(s) \_\_\_\_\_ is/are allowed.  
Claim(s) \_\_\_\_\_ is/are rejected.  
Claim(s) \_\_\_\_\_ is/are objected to.  
Claim(s) 38-120 are subject to restriction or election requirement.

#### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
  - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

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### DETAILED ACTION

In response to the Office action of paper #12, in which a restriction was set forth for the invention of a method of inhibiting KGF activity and a method of stimulating epithelial cells, Applicant chose to prosecute both inventions by paying for the examination of the second group of claims. In the originally submitted claims, the only compound that was claimed for this method was an antibody that binds to KGF. However, in the amendment of paper #14, Applicant has now added claims 121-131 which include additional compounds such as DNA probes, heparin and peptides that are based upon said antibody. These compounds constitute distinct inventions and are subject to restriction.

This application is subject to the transitional restriction provisions of Public Law 103-465, which became effective on June 8, 1995, because:

1. the application was filed on or before June 8, 1995, and has an effective U.S. filing date of June 8, 1992, or earlier;
2. a requirement for restriction was not made in the present or a parent application prior to April 8, 1995; and
3. the examiner was not prevented from making a requirement for restriction in the present or a parent application prior to April 8, 1995, due to actions by the applicant.

The transitional restriction provisions permit applicant to have more than one independent and distinct invention examined in the same application by paying a fee for each invention in excess of one.

Final rules concerning the transition restriction provisions were published in the *Federal Register* at 60 FR 20195 (April 25, 1995) and in the *Official Gazette* at 1174 O.G. 15 (May 2, 1995). The final rules at 37 CFR 1.17(s) include the fee amount required to be paid for each

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additional invention as set forth in the following requirement for restriction. See the current fee schedule for the proper amount of the fee.

Applicant must either: (1) elect the invention or inventions to be searched and examined and pay the fee set forth in 37 CFR 1.17(s) for each independent and distinct invention in excess of one which applicant elects; or (2) file a petition under 37 CFR 1.129(b) traversing the requirement.

*Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 121-131, drawn to a method of treating a patient by inhibiting KGF by the administration of a DNA probe, classified in class 514, subclass 44, for example.
  - II. Claims 121-131, drawn to a method of treating a patient by inhibiting KGF by the administration of heparin and a peptide that is based upon said antibody, classified in class 514, subclass 2.
2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because they have different modes of operation although they the same ultimate effect. The method using a DNA probe operates by inhibition of protein expression whereas the heparin/peptide most likely works by binding of the native protein to prevent its binding to its receptor or by binding to the receptor to prevent binding of the native KGF

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Furthermore, the inventions are not disclosed as capable of use together. Both of these methods are distinct from the already elected method of inhibiting KGF by an antibody in that the compounds are physically and functionally distinct, and therefore have different modes of operation, different functions, or different immediate effects.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the necessity for non-coextensive literature searches, restriction for examination purposes as indicated is proper.

3. A telephone restriction could not be offered because this restriction is Transitional and Applicant has the opportunity to pay for an additional invention. In addition, this second restriction was necessitated by Applicant's amendments to the claims.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

**Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your

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responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Donald E. Adams, Ph.D., Supervisory Patent Examiner at Donald.Adams@uspto.gov or 703-308-0570. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Saoud, Ph.D., whose telephone number is (703) 305-7519. The examiner can normally be reached on Monday to Friday from 8AM to 3PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached on (703) 308-2731. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

February 12, 1999

Christine Saoud, Ph.D.  
*Christine Saoud*  
Patent Examiner  
Art Unit 1646



# RESTRICTION ELECTION FACSIMILE TRANSMISSION

DATE:

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